CLYDESDALE® Spinal System
510(k) Summary
August 2012

SEP 18 2012

I. COMPANY:

Medtronic Sofamor Danek USA, Inc
1800 Pyramid Place
Memphis, Tennessee 38132

II. CONTACT:

Becky Ronner
Regulatory Affairs Specialist
Telephone: (901) 399-2757
Fax: (901) 346-9738

III. PROPRIETARY TRADE NAME: CLYDESDALE® Spinal System

IV. CLASSIFICATION NAMES: Intervertebral Body Fusion Device

COMMON NAME: Intervertebral Fusion with Bone Graft, Lumbar

CLASS: II

PRODUCT CODE: MAX (21 CFR 888.3080)

V. PRODUCT DESCRIPTION:

The CLYDESDALE® Spinal System is intended to help provide support in the intervertebral body space during fusion of vertebral bodies in the lumbar spine. This system is intended to be used with supplemental fixation.

The CLYDESDALE® Spinal System consists of PEEK cages of various widths and heights, which include tantalum markers. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allow them to be packed with autogenous bone graft.

VI. INDICATIONS FOR USE:

The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental

fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.

VII. Summary of the Technological Characteristics:

The subject system has the same indications, intended use and fundamental scientific technology as the previously FDA cleared predicate; CLYDESDALE® Spinal System K113528 (S.E. 12/20/2011). There has been no design, material, indication, sterilization changes to the previously cleared CLYDESDALE® Spinal System K113528 (S.E. 12/20/2011), the only change in the application is a modification to the labeling.

VIII. Identification of Legally Marketed Devices:

The fundamental scientific technology, design features and indications for use for the subject CLYDESDALE® Spinal System are identical to the predicate CLYDESDALE® Spinal System K113528 (S.E. 12/20/2011).

IX. Discussion of Non-Clinical Testing:

This modified labeling has been validated for the subject device by a cadaveric surgeon validation. Data from this validation supports the labeling modification. The intended use has not changed as the result of this labeling modification. This device is substantially equivalent to the predicate device.

X. Conclusion:

A validation and risk analysis was completed for the labeling change. Based on the validation, risk analysis and additional supporting documentation provided in this premarket notification, Medtronic believes the subject system demonstrates substantial equivalence to listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2012

Medtronic Sofamor Danek USA, Incorporated
% Ms. Becky Ronner
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K122591
Trade/Device Name: Clydesdale® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 23, 2012
Received: August 24, 2012

Dear Ms. Ronner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

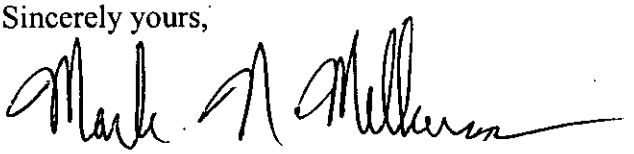
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K122591

Device Name: CLYDESDALE® Spinal System

Indications for Use:

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Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122591